

REMARKS

Claims 1-12, 14, 16, and 23-38 are pending in the above-identified application. Claims 1, 11, 24, and 32 are independent. Claims 23-38 have been added.

CLAIM REJECTION - 35 U.S.C. § 102

Claims 1, 2, and 5-8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Heidt et al. (U.S. Patent No. 5,336,467, hereinafter "Heidt"). Applicant respectfully traverses this rejection.

SUMMARY OF THE PRESENT INVENTION

The present invention, in a preferred embodiment, relates to a liquid sampler and an associated blood analyzer using the same. Applicant's invention is an improvement over previous analyzers and is of a smaller size, lower cost, and produces more accurate sampling of a very small volume on the order of 2 microliters (Specification, page 3, lines 18-21). In particular, since a pipette and a metering pump are directly connected to each other in a unitary relation without an intervention of a tube as a liquid sampler, the metering accuracy can be improved without expansion and contraction of the tube. Further the unitary arrangement of the pipette and metering pump prevents a change in the positional relationship between pipette and metering pump thereby improving metering accuracy. Finally, the unitary arrangement allows for a size reduction and cost reduction (see paragraph bridging pages 24 and 25).

In a liquid sampling system, as a preferred embodiment, liquid sampler 22 comprises a metering pump including a liquid sampler 22 having a cylinder 12, a piston 14, a linear actuator 16, a pipe head 18, and an electromagnetic valve 30, and a pipette 18. The metering pump and pipette are unitarily provided (see Figure 1). The liquid sampling system 10 further includes a vertical driving mechanism 25 and a horizontal driving mechanism 26 adopted to hold the sampler 22 for moving the sampler in direction z and x, respectively. A liquid surface detecting section 28 detects contact of a distal end of the pipette 18 with a liquid surface. A controlling section 45 controls operations of the actuator 16, the vertical and horizontal driving mechanism 25 and 26. A cleaning liquid supply section 34 is connected by a tube to the valve 30 fixed to the cylinder 12. Cylinder 12 has a cavity 13 coaxially formed therein, and two channels 15, 17 provided therein in communication with the cavity 13. The channel 15 communicates with the pipette 18 at a lower end of the cylinder 12, and channel 17 communicates with an outlet port of the valve 30 in an upper side face of the cylinder 12. Thus, in this embodiment, the cylinder 12 and pipette 18 are integrally formed of a stainless steel.

The present invention, in a preferred embodiment, includes a simplified blood analyzer employing the liquid sampler 22 (see Figure 4). The simplified blood analyzer is adopted to perform a blood analysis by employing a disposal pipette 55 detachably connected to the liquid sampler 22 for quantitatively sucking and discharging a blood specimen. After completion of analysis, the tip 55 is discarded so that the tip 55 need not be cleaned. Therefore, the

sampler 22 does not include the valve 30 nor the channel 17 shown in Figure 1. The sampler has the pipette 18, which may be eliminated.

Heidt

Heidt is directed to a chemical analyzer that includes a transport mechanism having a rotatable turntable adopted to hold a plurality of reagent test slides, a sample metering device, an incubator or temperature controller, a reflectometer and associated electronics and software (Abstract). In the metering assembly of Heidt, the assembly is preferably mounted on the underside of the base plate 48 (Heidt at column 21, lines 17-23; see also Figure 14, as well as details in Figures 15 and 16). The metering assembly includes a reversible DC stepper motor 270, which through the use of a lead screw 276 drives a syringe 296 having a plunger 300 and piston 304. When the stepping motor 270 is energized with the voltage of predetermined polarity and phasing, it will turn the lead screw 276, causing the movable block 290 to advance in a direction from the second support member 278 to the third support member block 280 (Heidt at column 22, lines 7-11). This in turn will drive the plunger 300 and piston 304 through the central bore of the syringe causing a serum sample collected by the pipette 18 to be expelled to the pipette tip 178. An air conduit 174 includes an air type female connector 312, which is adopted to be inserted onto male connector 314 mounted on a support bracket 294, which male connectors are in communication with the syringe 296 (Heidt at column 22, lines 57-61; see also Figure 16 having female connector 312 and Figure 14 having male connector 314).

As can be seen in Figure 1, the pipette inserted through opening 23. The pipette 18 has a tapered stainless steel end on which is fitted with a removable disposable tip 176 (Heidt at column 16, lines 55-58). The tip 176 has an upper end, which is formed with a series of radial extended supporting pins 178. Its disposable tip 176 extends through the bore of the pipette support ring 180 (see Figure 3) situated on the bridge bracket 58 (Heidt at column 16, lines 61-64). As can be seen in Figure 12, the tip 176 of the pipette extends below the bridge bracket 58 and directly above the film portion 124 of a test slide mounted on the turntable, which is rotated so that the slide is in alignment with the pipette. A vertically upward and downward movement is provided to the pipette 18 to ensure that a drop formed on the pipette tip will properly transfer to the film portion of the slide by capillary action (Heidt at column 17, lines 3-6).

Differences over Heidt

The liquid sampler as claimed in claim 1 includes, among other things, a metering pump including a cylinder having openings (for example, cylinder 12) and a cavity (for example, cavity 13), a piston inserted in the cavity (for example, piston 14), and a driving source for moving the piston (linear actuator 16). The liquid sampler further includes a pipette directly connected to one of the openings of the cylinder (pipette 18). Thus, the claimed invention encompasses a unitary relation between the metering pump's cylinder and pipette. As was stated above, such a unitary relation improves metering accuracy, which is particularly critical for sampling of volumes on the order of 2 μ L, and results in a reduction in size and cost of the overall assembly.

Applicant respectfully submits that the chemical analyzer and, in particular, the metering assembly of Heidt does not anticipate at least the liquid sampler of claim 1. Applicant submits that Heidt fails to teach or suggest at least the claimed pipette directly connected to one of the openings of the metering pump's cylinder.

As can be seen in Heidt, Figures 14, 15, and 16, the pipette 18, for example, is connected through a tube 20 to the chemical analyzer by way of a female connector 312 and an associated male connector 314. The chemical analyzer in turn contains, among other things, stepper motor 270 and syringe 296 for supplying serum to the pipette. In other words, the pipette and the metering assembly associated with the pipette are two separate devices connected by way of the tube 20. In the present claimed invention, on the other hand, the pipette is directly connected to an opening of a cylinder included in the metering pump. Further, expansion and contraction of the intervening tube reduces metering accuracy and has a larger size for the overall assembly. Thus, for at least these reasons, Applicant submits that each and every claimed element of claim 1 is not taught or suggested in Heidt.

With respect to dependent claims 2, and 5-8, at least for the reason above for claim 1, Applicant submits that Heidt does not teach each and every claimed element of those claims, as well. Further with respect to claim 2, since Heidt does not teach a pipette directly connected to an opening of the cylinder, Applicant submits that Heidt also does not teach wherein the pipette, the cylinder and the driving source are disposed in a coaxial relation. Thus, at least

for this additional reason, Applicant submits that Heidt fails to teach each and every claimed element of claims 2 and 5-8.

Claim Rejection – 35 U.S.C. 103: JP 2-080937A

Claims 3 and 4 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Heidt in view of JP 2-080937A. JP 2-080937A is relied on for teaching the claimed supplying a cleaning liquid into the cavity, and for controlling the supply thereof. However, JP 2-080937A does not at least make up for the above stated deficiency in Heidt. Thus, at least for the reasons above for claim 1, Applicant submits that all claimed elements are not taught or suggested by Heidt and JP 2-080937A, either alone or in combination. Further with respect to claim 4, Applicant submits that JP 2-080937A does not actually teach the claimed electromagnetic valve for controlling the supply of the cleaning liquid. Thus, at least for this additional reason, Applicant submits that the rejection fails to establish *prima facie* obviousness for claim 4.

Claim Rejection – 35 U.S.C. 103: JP 09-133686A

Claims 9-11, 21, and 22 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Heidt in view of JP 09-133686A.

The Office Action alleges that Heidt teaches the claimed invention except for a liquid surface detection circuit. JP 09-133686A is relied on for teaching the claimed liquid surface detecting section. However, for the same reason in the above for claim 1, Applicant submits that Heidt fails to teach at least the claimed liquid sampler comprising a metering pump including a cylinder having openings and a pipette directly connected to one of the openings of the

cylinder, i.e., unitary relation between the metering pump and the pipette. JP 09-133686A does not at least make up for that deficiency in Heidt. Thus, at least for the same reasons as above for claim 1, Applicant submits that all claimed elements of claims 9-11, 21, and 22 are not taught or suggested by Heidt and JP 09-133686A, either alone or in combination.

Claim Rejection – 35 U.S.C. 103: JP 09-133686A and Kogo

Claim 12 has been rejected under 35 U.S.C. 103 as being unpatentable over Heidt in view of JP 09-133686A and Kogo et al. (U.S. Patent 4,891,575, hereinafter Kogo). Kogo is relied on for teaching the claimed detection section. However, Applicant submits that Kogo does not at least make up for the above stated deficiency in Heidt and JP 09-133686A. Thus, at least for the reasons above for claim 11, Applicant submits that the rejection fails to establish *prima facie* obviousness for claim 12.

Allowable Subject Matter

Applicant thanks the Examiner for indicating that original claims 13-20 would be allowed if re-written into independent form.

New Claims

New claims 23-38 have been added. New independent claims 24 and 32 recite “a pipette connected to the metering pump” which Applicant submits that, in combination with the other claimed elements, distinguishes over the prior art of record. Features recited in the other added claims are disclosed in the present application. Thus, Applicant submits that no new matter has been added.

CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Robert W. Downs (Reg. No. 48,222) at the telephone number of (703) 205-8000, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully Submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

The paragraph beginning on page 6, line 12, has been amended as follows:

The term "pipette" herein means a tubular member capable of sucking and discharging a fluid, and a preferred example thereof is a stainless steel tube having a tapered distal end.

The paragraph beginning on page 11, line 10, has been amended as follows:

The cylinder 12 has a cavity 13 coaxially formed therein, and two channels 15, 17 provided therein in communication with the cavity 13. The channel 15 communicates with the pipette 18 at a lower end of the cylinder 12, and the channel 17 communicates with an outlet port of the valve 30 at an upper side face of the cylinder 12. In this embodiment, the cylinder 12 and the pipette 18 are integrally formed of a stainless steel. Alternatively, the cylinder 12 and the pipette 18 may be formed as separate members which are directly connected to each other without the intervention of a flexible member. Where the cylinder 12 is formed of a resin and the pipette 18 is formed of a stainless steel, for example, the cylinder 12 and the pipette 18 may be bonded to each other with an adhesive or the like.

IN THE CLAIMS:

The claims have been amended as follows:

1. (Amended) A liquid sampler comprising:

a metering pump including a cylinder having ~~opposite end~~ openings and a ~~cylindrical cavity~~, a piston inserted in the cavity ~~from one of the openings of the cylinder~~, and a driving source for ~~reciprocally and linearly~~ moving the piston; and

a pipette directly connected to ~~the other opening~~ one of the openings of the cylinder.

5. (Amended) A liquid sampler as set forth in claim 1, wherein the pipette is a disposable pipette ~~which directly connected to the other opening of the cylinder~~ in a detachable manner.

11. (Amended) ~~A blood~~ An analyzer comprising:

a liquid sampler which comprises a metering pump including a cylinder having ~~opposite end~~ openings and a ~~cylindrical cavity~~, a piston ~~inserted in the cavity from one of the openings of the cylinder~~, and a driving source for ~~reciprocally and linearly~~ moving the piston, and a ~~disposable pipette attached to the other opening~~ directly connected to one of the openings of the cylinder ~~in a detachable manner~~;

a driving mechanism for ~~moving~~ driving the liquid sampler ~~horizontally and vertically~~ to prepare a test sample;

~~a liquid surface detecting section for detecting contact of a distal end of the pipette with a liquid surface;~~

~~— a controlling section for controlling the pump driving source and the driving mechanism upon reception of a signal from the liquid surface detecting section;~~

~~— a specimen vessel for containing a blood specimen;~~

and

an analyzing section for analyzing a the test sample quantitatively dispensed out of the blood specimen from the specimen vessel by the liquid sampler.

12. (Amended) ~~A blood~~ An analyzer as set forth in claim 11, wherein the analyzing section comprises a detection member which includes a channel having an inlet and an outlet provided at opposite ends thereof and an orifice provided between the inlet and the outlet, and a detection section for detecting a change in impedance of the test sample when the test sample flows through the orifice.

14. (Amended) ~~A blood~~ An analyzer as set forth in claim 12 further comprising a controlling section for controlling the driving source and the driving mechanism,

~~wherein the analyzing section includes a reagent vessel for containing a predetermined volume of a reagent,~~

wherein the controlling section functions to control the pump driving source and the driving mechanism so as to cause the metering pump to quantitatively suck ~~the blood specimen~~ a liquid sample from ~~the a~~ specimen vessel for containing the liquid sample, quantitatively inject the sucked ~~specimen~~ liquid sample into ~~the a~~ reagent vessel for containing a predetermined volume of reagent to dilute the ~~specimen~~ sucked liquid sample, and quantitatively inject the diluted ~~specimen~~ liquid sample as the test sample into the inlet of the detection member

16. (Amended) ~~A blood~~ An analyzer as set forth in claim 12 further comprising a controlling section for controlling the driving source and the driving mechanism,

~~— wherein the analyzing section includes a reagent vessel for containing a predetermined volume of a reagent and a hemolyzing agent vessel for containing a hemolyzing agent,~~

wherein the controlling section functions to control the pump driving source and the driving mechanism so as to cause the metering pump to quantitatively suck ~~the blood specimen~~ a liquid sample from ~~the a~~ specimen vessel for containing the liquid sample, quantitatively inject the sucked ~~specimen~~ liquid sample into ~~the a~~ reagent vessel for containing a predetermined volume of reagent to dilute the ~~specimen~~ sucked liquid sample, suck ~~the a~~ hemolyzing agent from ~~the a~~ hemolyzing agent from ~~the a~~ hemolyzing agent vessel for containing the hemolyzing agent, inject the sucked hemolyzing agent into the reagent vessel to hemolyze the diluted ~~specimen~~ liquid sample, and

quantitatively inject the hemolyzed ~~specimen~~liquid sample as the test sample into the inlet of the detection member.

New claims 23-38 have been added.